House Health and Human Resources Committee Amendment #1

Amendment No. 1 to HB1410

FILED
Date _____
Time _____
Clerk _____
Comm. Amdt. _____
_____

Armstrong
Signature of Sponsor

AMEND Senate Bill No. 1360* House Bill No. 1410

by deleting all language after the enacting clause and by substituting instead the following language:

SECTION 1. Tennessee Code Annotated, Section 39-17-421, is amended by deleting such section in its entirety and by substituting instead the following:

Section 39-17-421.

(a) Except as provided in title 53, chapter 10, part 2, it shall be unlawful for any pharmacist, or any pharmacy technician or any pharmacy intern under the supervision of a pharmacist who dispenses prescriptions, drugs, and medicines to substitute any drug or device different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber as defined in § 63-10-204.

(b) A violation of this section is a Class C misdemeanor.

SECTION 2. Tennessee Code Annotated, Title 53, Chapter 10, is amended by deleting Part 2 in its entirety and by substituting instead Sections 3 through 12 of this act as new Part 2.

SECTION 3. This act shall be known and may be cited as the "Tennessee Affordable Drug Act of 2005".

SECTION 4. The general assembly declares it to be the public policy that in order to lower the cost of prescription drugs to its citizens, pharmacists may substitute less costly generic or therapeutic alternate drugs or drug products for higher priced brand name or trade name drugs or drug products.

SECTION 5. As used in this part unless the context otherwise requires:

(1) "Brand name" means the registered trademark name of a drug or drug product given by its manufacturer, labeler or distributor;

(2) “Finished dosage form” means that form of a drug which is, or is intended to be, dispensed or administered to a patient and requires no further manufacturing or processing other than packaging, reconstitution or labeling;

(3) “Generic equivalent” means a drug product which has the same established name, active ingredient(s), strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (i.e. strength, quality, purity, and identity), but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, preservatives), and expiration time;

(4) “Therapeutic alternate” means a drug or drug product with a different chemical structure than the drug or drug product prescribed but which is of the same pharmacological and/or therapeutic class, and having the same or substantially similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;

(5) “Prescriber” means an individual authorized by law to prescribe drugs; and

(6) “Drug plan compliance” means substitution with a therapeutic alternate from a list of drug or drug products containing both brand name and generics that arranged by therapeutic and/or pharmacological classes, commonly referred to as a preferred drug list or a formulary.

SECTION 6.

(a) The prescriber shall allow for substitution with a generic equivalent of a brand name drug or drug product under all circumstances except as provided in this subsection.

(1) The prescriber determines the medical necessity of a brand name drug or drug product due to:

(A) Adverse reaction previously experienced by the patient to a generic equivalent,

(B) A generic equivalent has previously been demonstrated as ineffective for the patient; or

(C) Any other clinically based prescriber determined need.

(2) A generic equivalent is not available.

(b) If the prescriber determines a brand name drug or drug product is medically necessary for a patient, the prescriber shall, in the prescriber's own handwriting, place the instruction showing intent upon the prescription at the time it is prepared and issued. For the purposes of this subsection, instruction showing intent may include, but not be limited to, the following language:

(1) “Brand name medically necessary”, “dispense as written”, “medically necessary”, “brand name”, “no generic”;

(2) Any abbreviation of the language in the subsection above; or,

(3) Any other prescriber handwritten notation, such as circling a preprinted dispense as written on the prescription order, that clearly conveys the intent that a brand name is necessary for this patient.

(c) If the prescriber determines a brand name drug or drug product is medically necessary for a patient and that prescription order is issued verbally, the prescriber shall alert the pharmacist that use of the brand name drug or drug product is medically necessary for the patient.

(d) If the prescriber determines the brand name drug or drug product is medically necessary for a patient and that prescription is sent to the pharmacist through electronic technology or through facsimile, the prescriber shall place the proper instruction on the prescription at the time it is prepared electronically.

(e) Nothing in this section shall be construed to prevent a prescriber from informing a patient of the prescriber’s professional opinion as to the capabilities, effectiveness and acceptability of any drug.

SECTION 7.

(a) The governor shall appoint the Task Force on Affordable Drugs for Tennesseans.

(b) The task force shall consist of seven (7) persons appointed by the governor including:

(1) Three (3) practicing physicians, two (2) of whom shall be chosen from a list of five (5) candidates submitted by the Tennessee Medical Association, and one (1) who shall be chosen from a list of three (3) candidates submitted by the Volunteer State Medical Association;

(2) Three (3) pharmacists, one (1) who shall be engaged in the retail distribution of prescription drugs and drug products and shall be chosen from a list of three (3) candidates submitted by the Tennessee Pharmacists Association, and two (2) who shall have experience and expertise in the development of drug plans, commonly known as preferred drug lists or formularies, from a list of four (4) candidates submitted by the Tennessee Pharmacists Association;

(3) One (1) general consumer who shall be a resident of the state.

(c) The governor shall appoint a chair and vice chair and call the first meeting to order. The task force will be charged with determining the therapeutic classes within which substitution with therapeutic alternates could appropriately occur, specific or general recommendations that the practices of medicine and pharmacy could implement to reduce prescription drug costs to patients while not diminishing quality of care, and other such matters as the governor may direct.

(d) All appointees of the task force shall serve with no compensation for their service on the task force.

(e) The task force shall report to the board of medical examiners, board of pharmacy, and the board of osteopathic examination by January 1, 2006, for a review and comment for a period not to exceed thirty (30) calendar days. The aforementioned boards shall forward their comments to the governor, commissioner of finance and administration, the commissioner of health, the commissioner of commerce and insurance, the chairs of the house and senate commerce committees, the chair of the house health committee and the chair of the senate general welfare committee.

(f) Nothing in this act shall invalidate any current or pending agreements or processes otherwise permitted by law.

SECTION 8.

(a) When a pharmacist receives a written, verbal, electronic or facsimile prescription order and the prescriber has not noted medical necessity of the brand name prescribed as required in Section 6, the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient's drug plan, except as provided in subsections (c) and (d).

(b) A pharmacist shall make a reasonable attempt to notify a prescriber if a generic equivalent has become available since the last dispensing of a prescription and if authorized by the prescriber the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient's drug plan. If a pharmacist has reason to believe that the brand name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent, the pharmacist shall fill the prescription with the brand name drug or drug product.

(c) When a pharmacist receives a written, verbal, electronic, or facsimile prescription order and the prescriber has not noted medical necessity of the brand name as required in Section 6, the pharmacist shall dispense the appropriate drug pursuant to subsection (a) of Section 8 unless the patient is individually paying the entire cost of the prescription at the time of dispensing and objects to any substitution.

SECTION 10. A pharmacist who selects a generic equivalent for substitution pursuant to Sections 6 has the same responsibility for the selected drug as such pharmacist would in dispensing a prescription for the drug prescribed by its trade or brand name.

SECTION 11.

(a) The manufacturer, packager, or distributor of any human use legend drug sold, delivered or offered for sale in the state of Tennessee must have printed on the label of the immediate container of the drug the name and address of the manufacturer, packager, or distributor of the finished dosage form of the drug.

(b) The pharmacist shall notify the patient of the substitution with a generic equivalent by noting the substitution on the prescription label.

(c) This provisions of this section shall not apply to prescriptions dispensed for inpatients of a hospital, a nursing home or an assisted care living facility as defined in § 68-11-201.

SECTION 12. In making substitutions as allowed by this part, the pharmacist may use drugs and drug products manufactured within the territorial limits of any one of the states of the United States or any other country if such products have been approved by the federal food and drug administration.

SECTION 13. Nothing in this act shall be construed as authorizing any person or entity to interfere with a prescriber's obligation to exercise independent medical judgment in rendering healthcare services to patients.

SECTION 14. If any provision of this act or the application thereof to any person or circumstance is held invalid, then such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 15. This act shall take effect upon becoming a law, the public welfare requiring it.